Express Mail Label No. EV 326 986 266 US Attorney Docket No. 55600-8013.US01

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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| N RE APPLICATION OF: | |
| Sokawa & Liu | EXAMINER: Unassigned |
| APPLICATION NO.: Unassigned | ART UNIT: Unassigned |
| FILED: Concurrently Herewith | |
| FOR: **METHOD OF TREATMENT USING INTERFERON-TAU** | |

## PETITION TO MAKE SPECIAL

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In accordance with 37 CFR 1.102 and the procedure set forth in MPEP §708.02, section VIII, for accelerated examination procedure, the applicant requests, prior to examination, that the above-identified application be granted special status.

The applicant submits that the present petition and accompanying documents meet all of the requirements set forth at MPEP §708.02, section VIII. Specifically, the applicant hereby submits the following:

(a) the present petition to make special, accompanied by the fee set forth in 37 CFR 1.17(i) ($130.00);

(b) a preliminary amendment intended to limit the claims in the application to a single invention;

(c) a statement that a pre-examination search was made by applicant's agent, listing the field of search; and

(d) a detailed discussion of the references deemed most closely related to the subject matter encompassed by the claims, which points out, with the particularity required by 37 CFR 1.111 (b) and (c), how the claimed subject matter is distinguishable over the references.

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The applicant requests that, if the present request is defective in any respect, the applicant be given an opportunity to perfect the request, as provided in MPEP §708.02, section VIII.

The Commissioner is authorized to charge any underpayment of fees herein (or credit any overpayment) to Deposit Account No. 50-2207.

Respectfully submitted,

Judy M. Mohr

Date: 21 November 2003

Judy M. Mohr
Registration No. 38,563

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(650) 838-4300

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**STATEMENT REGARDING PREEXAMINATION SEARCH IN CONNECTION WITH PETITION TO MAKE SPECIAL**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Judy M. Mohr, an authorized agent in the above-identified application, hereby declare that a pre-examination search has been made in accordance with to MPEP §708.02, section VIII, in the following databases and search queries:

A. Searches Performed and References Submitted

The World Patent Index and Medline were each searched, with separate search queries directed to:

(a) interferon tau (hereinafter IFNτ or IFN-tau) plus oral delivery or administration;

(b) 2', 5'-oligoadenylate synthetase (hereinafter "OAS") or OAS plus interferon.

From these searches, the U.S. patents and published applications, foreign patents and applications, and journal publications listed in the attached IDS Form 1449 were selected for review.

We also reviewed the Information Disclosure Statements and accompanying Forms-1449 submitted during the course of prosecution of the U.S. patent applications upon which this case claims priority, and selected from the earlier Information

Disclosure Statements any additional references earlier cited which were deemed pertinent to the claims in the present application. The selected references are included in the present IDS Form 1449.

We also reviewed International Search Reports, International Preliminary Exam Reports, and Office actions in corresponding foreign application of U.S. patent applications to which this application claims priority, and selected from the earlier Information Disclosure Statements, any additional references earlier cited which were deemed pertinent to the claims in the present application. The selected references are included in the present IDS Form 1449.

Copies of the references listed in the current Form 1449 that were not submitted in a priority application are enclosed herewith; specifically documents identified by Cite No. on the Form 1449 as 10, 12, 14, 17-19, 21, 23-24, 27, 34-37, 46, 51, 55, 59, 62-64, 66, 69-72, 77, 79, and 85 are enclosed. To ease review of the most pertinent references discussed below, copies are included even though the document may have been earlier submitted in a priority application. The presently submitted Form 1449 includes documents newly identified by the searches described above, as well as all documents cited on the earlier-filed Forms 1449 of the priority applications and all documents cited on reports and actions in the foreign counterpart applications of the U.S. priority applications.

B. Discussion of the Most Pertinent Art

B1. References related to oral administration of IFNτ

1. U.S. Patent No. 5,906,816 for "Method for Treatment of Autoimmune Diseases", issued May 25, 1999, filed March 16, 1995.

2. U.S. Patent No. 5,958,402 for "Antitumor Therapy Using Ovine or Bovine Interferon-tau", issued September 28, 1999, filed May 31, 1995.

3. U.S. Patent No. 6,060,450 for "Method for Treatment of Autoimmune Diseases", issued May 9, 2000, filed May 25, 1999.

4. U.S. Patent No. 6,372,206 for "Orally-Administered Interferon-tau Compositions and Methods", issued April 16, 2002, filed March 15, 1996.

5. Soos, J.M., *et al*, "Oral Feeding of interferon tau can prevent the acute and chronic relapsing forms of experimental allergic encephomyelitis," *J. Neuroimmunology*, 75:43-50., 1997.

6. PCT Patent Application No. PCT/US96/03472 for "Method for Treatment of Autoimmune Diseases Using Interferon-tau", filed March 15, 1996.

7. PCT Patent Application No. PCT/US93/10016 for "Interferon Tau Compositions and Methods of Use", filed October 19, 1993.

8. PCT Patent Application No. PCT/US90/01122 for "Composition for the Inhibition of Tumors and for the Non-Cytotoxic Inhibition of Replication of Viruses", filed March 1, 1990.

All of the above references disclose the use of ovine IFNτ for the treatment of a variety of conditions, including autoimmune disorders, such as multiple sclerosis, viral infection and cancer. Although the references suggest administration of IFN-tau by oral administration, among a variety of modes of administration, they do not specifically teach targeting the IFN-tau to the intestinal tract of a human subject. Nor do any of the references teach administering, as an effective amount, a dose of IFN-tau that is effective to produce a measurable increase in the subject's serum 2', 5'-oligoadenylate synthetase (OAS) level, relative to the OAS level in the subject in the absence of IFN-tau administration. More specifically, none of the references mentions OAS, or any other quantifiable blood measurement, as a potential indicator of an effective IFN-tau dose. Nor do any of the references show or suggest continuing to administer such an effective dose despite changes in measurable OAS blood levels.

B2. References related to OAS levels in response to IFNs

1. Adah, S. A. *et al.*, "Chemistry and Biochemistry of 2',5'-Oligoadenylate-Based Antisense Strategy", *Current Medicinal Chemistry* 8:1189-1212, 2001.

Adah *et al.* describe a 2', 5'-oligoadenylate antisense capable of inducing RNA cleavage. Adah *et al.* state that the 2',5'-oligoadenylate system is an RNA degradation pathway is part of interferon action against certain viruses. Cells exposed to interferon induces enhanced levels of 2',5'-oligoadenylate synthetase, initiating a cascade that results in degradation of viral mRNA. Adah *et al.* nowhere show or suggest that INF-tau,

a non-human, non-endogenous protein, would induce production of 2',5'-oligoadenylate synthetase, particularly after administration to the intestine of a human patient.

2. Nakajima, A. and Sokawa, Y., "Induction of Blood 2',5'-Oligoadenylate Synthetase Activity in Mice by Gastric Administration of Ovine IFN-tau", *Journal of Interferon and Cytokine Research* 22:397-402, 2002.

This paper is by the named inventor in this case, Y. Sokawa, and is not an effective reference because the pertinent disclosure from this paper is included priority application serial no. 10/346,269, which claims the benefit of 60/349,58, filed January 16, 2002, and in the present application.

3. Samuel, Charles E., "Interferon-Induced Proteins and Their Mechanisms of Action", *Hokkaido J. Med Sci* 69(6):1339-1347, 1994.

Samuel describes four cellular pathways induced by interferon proteins. One of the pathways involving IFN-regulated proteins is the 2',5'-oligoadenylate synthetase response. The disclosure in Samuel is limited to the type I interferons alpha, beta, and omega. IFN-tau is nowhere mentioned.

4. Schroder, H. C. *et al.*, "(2'-5') Oligoadenylate and Intracellular Immunity Against Retrovirus Infection", *Int. J. Biochem.* 24(1):55-63, 1992.

Schroder *et al.* are concerned with strategies for enhancing the natural 2',5'-oligoadenylate synthetase system in HIV-infected patients. Schroder *et al.* note that interferon induces the expression of the 2',5'-oligoadenylate synthetase gene and that application of interferons may be a strategy for treatment of HIV (page 56, Col. 1, lines 22-34). Schroder *et al.* mention IFN-alpha and IFN-gamma (page 60, Col. 2, final paragraph), but nowhere disclose IFN-tau.

5. Castelli, J. *et al.*, "The 2-5A system in viral infection and apoptosis", *Biomed & Pharmacother* 52:386-390, 1998.

Castelli *et al.* disclose that interferon treatment of cells leads to an increase in 2',5'-oligoadenylate synthetase levels and in the level of 2-5A dependent RNase L. Apoptosis due to RNase L activity and the 2',5'-oligoadenylate synthetase system provide defense against viral infections in multicellular organisms. The teaching in Castelli *et al.* relating to the involvement of interferons in induction of the 2',5'-

oligoadenylate synthetase system is limited to "Type I interferons, comprised of two isoforms (α and β)..." (page 387, Col. 2, lines 19-21). Nowhere is IFN-tau mentioned.

Respectfully submitted,

Judy M

Date: 21 November 2003

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